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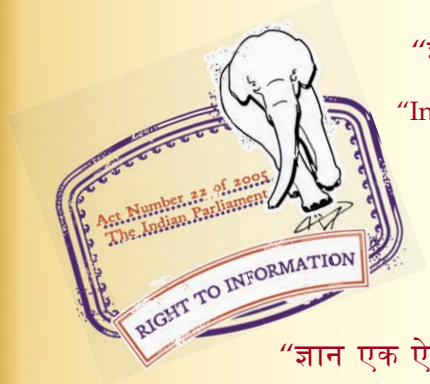
IS 6778 (1989): Thoracic Surgery Instruments - Forceps, Lung, Duval's Pattern [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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IS 6778 : 1989

(Reaffirmed 2005)

Indian Standard

THORACIC SURGERY INSTRUMENTS — FORCEPS, LUNG, DUVAL'S PATTERN — SPECIFICATION

(First Revision)

भारतीय मानक

छाती सम्बन्धी शल्यक्रिया उपकरण — चिमटियाँ, फेफड़ा, डुवल नमूने — विशिष्टि

(पहला पुनरीक्षण)

UDC 615·472·4 : 616·24-089 : 617·54

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

July 1990

Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1972. In this revision, tolerances on various dimensions have been specified, an additional test for flexibility has been incorporated and the clauses on surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

THORACIC SURGERY INSTRUMENTS — FORCEPS, LUNG, DUVAL'S PATTERN — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard prescribes requirements and tests for Duval's pattern, lung forceps used in thoracic surgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	*Title*
1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (*second revision*)
3642 : 1978	General requirements for surgical instruments (*first revision*)
4905 : 1968	Methods for random sampling
6528 : 1972	Specification for stainless steel wire
6603 : 1972	Specification for stainless steel bars and flats
7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIAL

3.1 The instrument shall be made of stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS 6603 : 1972.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the instrument shall be as shown in Fig. 1.

4.2 Tolerances

Tolerances on linear dimensions shall be as given below:

±0·05 mm on dimensions up to 2·0 mm.

±0·1 mm on dimensions above 2·0 mm and up to 5·0 mm.

±0·2 mm on dimensions above 5·0 mm and up to 20·0 mm.

±0·5 mm on dimensions above 20·0 mm and up to 50·0 mm.

±1·0 mm on dimensions above 50·0 mm and up to 100·0 mm.

±2·0 mm on dimensions above 100·0 mm.

4.2.1 The two halves of the instrument shall, however, not differ at any dimension and shall match with each other perfectly.

5 MASS

5.1 The mass of the instrument shall be 30 ± 3 g, 35 ± 4 g and 40 ±4 g for baby, small and large size respectively.

6 HEAT TREATMENT

6.1 The instruments shall be uniformly hardened and tempered to a hardness of 400 HV to 460 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

6.2 Mating surfaces on the same instrument, such as opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

7 WORKMANSHIP

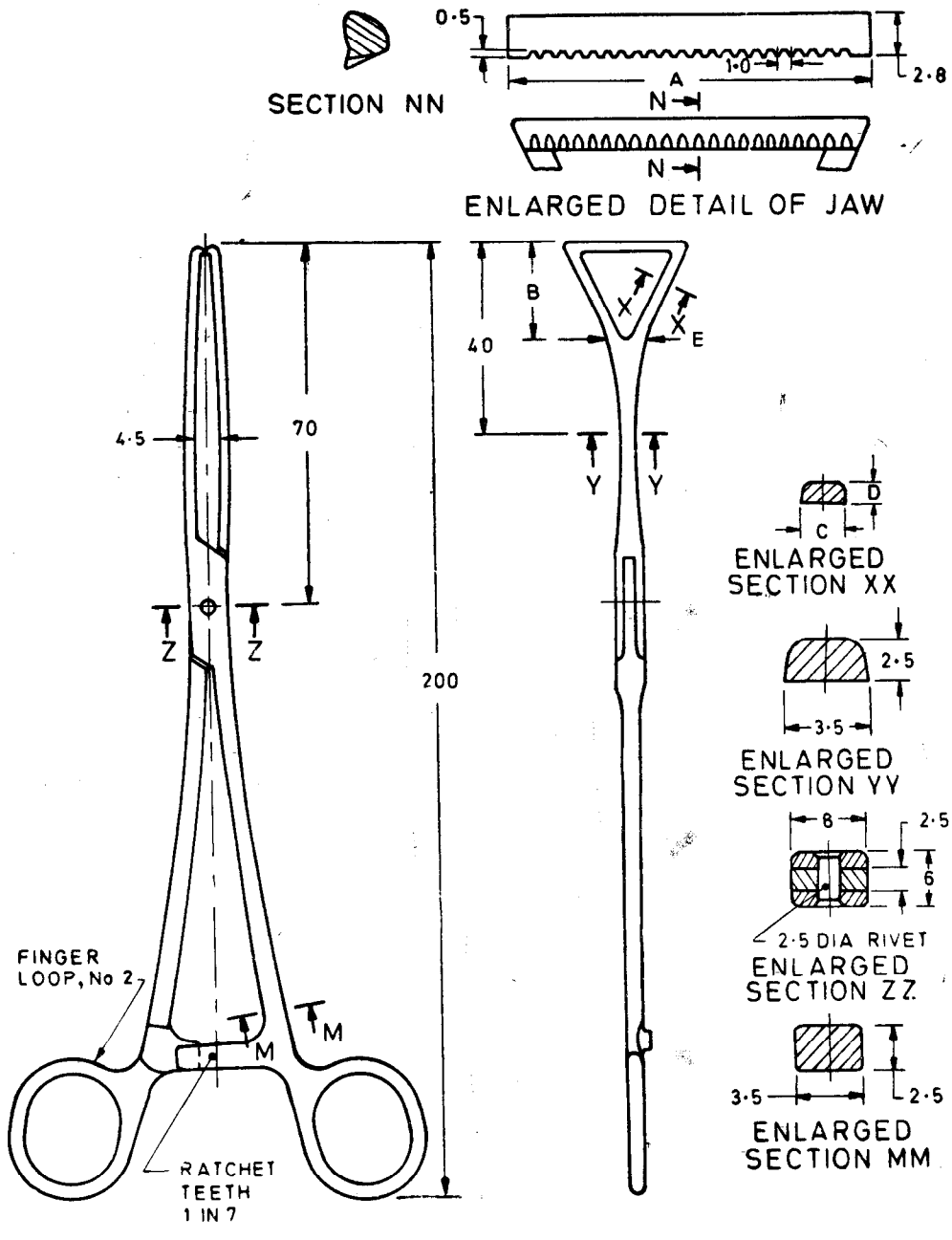
7.1 The forceps shall be symmetrical and balanced, and the opening and closing movement shall be smooth and jerk free, with the tips parallel throughout.

7.2 The joint shall conform to the relevant requirements of **6** of IS 3642 : 1978.

7.3 The serrations on the jaws shall be on the perpendicular edge of the tip and truncated, and shall conform to the relevant requirements of Section 1 of IS 3642 : 1978 except that the test for engagement of the jaws shall be as in **9.1.**

7.4 The ratchet teeth shall be with combination of 1 in 7 and shall conform to Section 3 of IS 3642 : 1978.

7.5 The finger loops shall be in accordance with the relevant requirements of Section 5 of IS 3642 : 1978.



Size	*A*	*B*	*C*	*D*	*E*
Baby	12·5	16	1·7	1.3	4
Small	17·0	20	2·0	1·5	5
Large	25·0	25	2·5	2·0	7

All dimensions in millimetres.

FIG. 1 FORCEPS, LUNG, DUVAL'S PATTERN

8 SURFACE CONDITION

8.1 General

All surfaces shall be free from sharp edges, pores, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

8.2 Surface Finish

The surface finish of the instrument shall be reflection-reducing, for example, satin finish, and matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

8.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (*v/v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

9 TESTS

9.1 Test for Engagement of Jaws

When the first step of the ratchet is engaged, the forceps shall be symmetrical on the centre line and the serrations shall approximate to a gap of 1 mm. The interdigitation shall complete at the second ratchet engagement. The serrations shall engage perfectly and truly.

9.2 Load Closure Test

By fixing one finger loop of the forceps in a vice, load shall be applied at the free finger loop by means of a pan or spring balance. The load at which the first ratchet just engages shall be noted. The load required to close the forceps on the first step of the ratchet shall be 2·0 ± 0·5 N (200 ± 50 gf approximately).

9.2.1 The tips shall be able to hold a clear goat or sheep intestine, when the first ratchet is engaged. The intestine shall be held firmly and shall not slip when slight pull is applied.

9.3 Flexibility Test

9.3.1 Each arm of the forceps shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be deflected by 15 mm in the same plane as that of finger loop. The arm shall not take a permanent set or break.

9.3.2 A stainless steel wire of 4 mm dia, conforming to Designation 04Cr18Ni10 of IS 6528 : 1972, shall be placed between the tips of the instrument jaws and the instrument fully closed to the last ratchet position. The instrument shall then be left in this position for 3 hours at room temperature. After the test, no distortion, cracks or any other permanent modifications in the instrument shall be visible.

9.4 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

10 MARKING AND PACKING

10.1 The instruments shall be legibly and indelibly marked with the indication of the source of manufacture, the words 'stainless steel' or letters 'ss', and the country of manufacture.

10.2 Each instrument shall be wrapped in a suitable cushioning material like folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

10.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

10.3 The packages shall be marked with the name and size of the instrument indication of the source of manufacture, the words 'stainless steel', and the country of manufacture.

11 SAMPLING

11.1 The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A

ANNEX A
(*Clause* 11.1)
SAMPLING OF FORCEPS, LUNG, DUVAL'S PATTERN

A-1 LOT

A-1.1 In any consignment, all the instruments of the same size, produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling

(*Clauses* A-2, A-3.1 *and* A-3.2)

Lot Size (1)	Sample Size (2)	Sub-sample Size (3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual), and tested for mass and engagement of jaws. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements, if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1.** Each instrument in the sub-sample shall be subjected to hardness, load closure, flexibility and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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The use of the Standard Mark is governed by the provisions of the *Bureau of the Indian Standards, Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

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Revision of Indian Standards

Indian Standards are reviewed periodically and revised, when necessary and amendments, if any, are issued from time to time. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition. Comments on this Indian Standard may be sent to BIS giving the following reference:

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